National Institute for Health and Care Excellence

Review Guide to the Methods of Technology Appraisals Addendum - 2014

Comments [DRAFT 3 RESPONSE]

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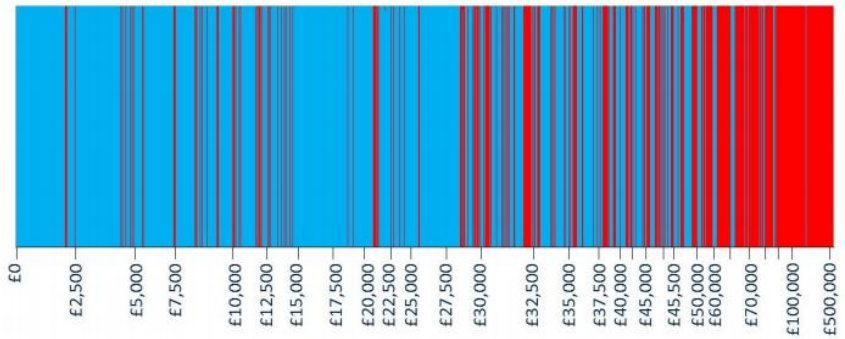
	Consultation questions
1 Does proportional QALY shortfall appropriately reflect burden of illness?	**No**. We have long standing concerns about the ability of the tools that underpin QALYs to capture what is important to patients and carers, especially in cancer. Relying on QALYs again as part of proportionate shortfall compounds these concerns. Whilst we can understand the pragmatic desire to use the QALY as it is familiar, we hope that NICE will facilitate, and Appraisal Committee members will be open to and reflect upon, patient organisations and expert patient and carer evidence on burden of illness. Other organisations representing patients with cancer have concerns too, including the Cancer Campaigning Group (CCG), the Rarer Cancer Foundation (RCF) and Patients Involved in NICE (PIN).
2 Does absolute QALY shortfall provide a reasonable proxy for wider societal impact of a condition?	**No.** See comments to 1 above. In addition, the proxy status is highly tenuous given the claim made that it reflects a 'person's capacity to engage with society'. We ask, as we have previously, that NICE instead introduce the relevant social sciences (and their practitioners) into both the assessment and appraisal environments.

3 Does a maximum weight of 2.5 in circumstances when all modifiers apply function as a reasonable maximum?	**No**. We believe that this suggestion is based on a default to selected NICE Appraisal Committees' decisions made in the past using End of Life criteria. It is not grounded in empirical evidence nor is it a reflection of the priorities of society or patients. Analysis suggests that NICE Committees have accepted not only much higher cost per QALYs, but also rejected much lower cost per QALYs (as seen in figure 1 below). This illustrates the importance of not just the economics but other factors. We want to keep this flexibility, not arbitrarily constrain it. Figure 1: Impact of ICER ranking on recommendations  **Notes:** Decisions are ranked by ICER, with NICE decisions to "recommend" shown in blue and to "reject" shown in red. For clarity, only the first five datasets of randomly-sampled ICERs are shown. H. Dakin et al., The influence of cost-effectiveness and other factors on NICE decisions. Office of Health Economics, November 2013
4 Should we allocate specific 'weights' to each of the 'modifiers' so that they add up to a maximum of 2.5? If so, do you have a view on what weight should be added in each case	**No**. Whilst we support greater transparency in the establishment of the relative importance of the modifiers in a particular appraisal and this informing an Appraisal Committee's decision making, we believe that it would be premature to allocate specific weights. This would require significant work to build the empirical evidence base that would be required, and would be meaningless without significant patient and public involvement. We believe that improving the deliberative process with greater emphasis on, and enhancement of, the role of the lay representative and giving voice to patient & carer experts and patient & carer representatives, is a more pressing issue. This is the opportunity we see with proposals for VBA.

5 Will the approach outlined in this document achieve the proposed objectives of improving consistency, predictability and transparency in the judgements made by our independent Appraisal Committees when they consider the clinical and cost effectiveness of health technologies?	**No**. We have previously asked NICE to 'road test' their approach with patients in our briefing paper on VBA available here: http://www.cancer52.org.uk/wp-content/uploads/2009/10/Cancer52-VBA-NICE-Do-It-Their-Way.pdf. Comments from Andrew Dillon in the 17th February 2014 interview in the Times suggest that there is internal work at NICE that does just this. We wrote to Andrew Dillon to ask for more details on the 26th February 2014. Andrew has not replied to us to date. If, as we believe, this work has been undertaken, we urge NICE to demonstrate its commitment to transparency and publish it. This would, of course, be on an illustrative only basis. If we have misinterpreted Andrew's comments and this work has not been completed, an alternative, given the pressing timelines, would be to confer, as with the Process & Methods of the Highly Specialised Technologies Programme, interim status on the revised TA Methods and Process Guides for either some fixed timeline, or number of appraisals, prior to a consultation and review exercise being undertaken. On transparency, we, as do the Cancer Campaigning Group (CCG), ask that NICE makes it clear how Appraisal Committees have drawn on evidence of Burden of Illness and Wider Societal Impact in future decisions. For example, by adding additional rows to the table used to summarise the Appraisal Committees' key conclusions.
6 Are there any risks which might arise as a result of adopting the value-based assessment approach as outlined above? If so, how might we try to reduce them?	**Yes**. We share the concerns of many that there are risks in making these changes. Key concerns include: - Loss of End of Life as an explicit criterion – raising the possibility of leaving patients with rare cancers who are near the end of their life with fewer treatment options. We value transparency, and whilst we understand the argument that the approach could, in effect, still permit a higher weight for End of Life circumstances, the proposed VBA approach runs the risk of being more opaque than the current approach - Risk of discriminating against those who do not work (which may be a function of their illness and no reflection on their willingness to work) – as NICE recognises age is invariably reflected in any VBA evaluation.

7 Are there any other comments you wish to make?		Please enter these comments in the table below
Paragraph Number Primarily Related to your Comment (please enter only one) Indicate **'general'** if your comment relates to the whole document	**Other Paragraph Numbers Related to your Comment**	**Comments** **Please insert each new comment in a new row.** **Please do not paste other tables into this table, as your comments could get lost – type directly into this table.**
General		We believe that there is an opportunity to more fully reflect the impact of disease and the potential benefits of treatment through the additional modifiers of Burden of Illness and Wider Societal Benefit. We believe that patients, and their carers, with their real world experience, are best placed to articulate these impacts and that we should be given the opportunity (and support) to provide evidence on these to the Appraisal Committee both as patient and carer experts and as representatives of organisations for patients and carers. We have set out our proposals in more detail here: http://www.cancer52.org.uk/wp-content/uploads/2009/10/Overview-of-Cancer52-response-to-NICE-consultation-on-Technology-Appraisals-Process-Guide1.pdf and here http://www.cancer52.org.uk/wp-content/uploads/2009/10/TAProcessGuidesConsultationComments-Cancer52-Final.pdf
General		We believe that there should be a full and open approach to evaluation of these changes as we have already said in our briefing papers on VBA available here: http://www.cancer52.org.uk/wp-content/uploads/2009/10/Cancer52-VBA-NICE-Do-It-Their-Way.pdf and here: http://www.cancer52.org.uk/wp-content/uploads/2013/03/Cancer52-Position-Statement-on-Value-Based-Pricing-Sept-Update.pdf This would be facilitated by the interim status we suggest as above.

General		We are concerned that much of the discussion relates to 'average' patients (for instance, the average age of patients which, for example, would not reflect the life time benefits for young people with cancer, provided in the illustrative table available at: http://www.nice.org.uk/media/FE3/97/Illustrative_TA_list_and_QALY_shortfall.pdf). However, as our knowledge of genetics and its relationship to disease increases and as opportunities are exploited to tailor treatments (e.g. BRCA testing may influence future decisions for drugs to treat ovarian cancer), decisions are needed for sub-groups of patients. We're unclear how VBA fits alongside this more stratified approach that is already occurring in clinical practice.
General		We believe that the changes need to be considered alongside the original objectives for Value Based Pricing. These were to: - improve outcomes for patients through better access to effective medicines; - stimulate innovation and the development of high value treatments; - improve the process for assessing new medicines, ensuring transparent, predictable and timely decision-making; - include a wide assessment, alongside clinical effectiveness, of the range of factors through which medicines deliver benefits for patients and society; - ensure value for money and best use of NHS resources. (Source: http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_122793.pdf) We do not see a clear link between the NICE proposals and the objectives set out by the Department of Health.

General		We believe NICE needs to take full advantage of the introduction of VBA to be bold in their revision of the Methods and Process guides. In particular the current proposals seem to offer no answer to the conflict between a system that recognises the requirement that it be timely in its process yet rigorous in its requirement for evidence. We believe NICE should build on the existing options of Only in Research and Approval with Research. These are also in line with the broader changes affecting decisions on new medicines, seen with the European Medicines Agency's pilot of Adaptive Licensing, the MHRA's Early Access to Medicines Scheme and Commissioning through Evaluation from NHS England. The rationale for and objectives underpinning these speak to conditionality, flexibility, dynamism and the real world. NICE should align with these features and respond appropriately in the same way as it has accorded recognition to the need to accommodate factors other than the clinical and economic in its assessment and appraisal work.
General		Just as we note above, one of the ambition for the reforms was to stimulate innovation. Innovation remains an area where everyone agrees on its importance, but beyond that it's hard to see how innovation will be encouraged nor that it will be more clearly identified as a factor in Appraisal Committees decisions.

Please email this form to: 2014VBAmethods@nice.org.uk

Closing date: Friday 20 June 2014 5pm

PLEASE NOTE: NICE reserves the right to summarise and edit comments received during consultations, or not to publish them at all, where in the reasonable opinion of NICE, the comments are voluminous, publication would be unlawful or publication would be otherwise inappropriate.